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EXAMINER

NOGUEROLA, ALEXANDER STEPHAN

ART UNIT	PAPER NUMBER
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1743

DATE MAILED: 10/01/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

plicant(s)

09/728,378

UPDYKE ET AL.

Examiner

Art Unit

ALEX NOGUEROLA

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-- The MAILING DATE of this communication appears on the cover sheet with the corresponding address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 November 2000 and 02 April 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 23-66 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 23-66 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4. 6) ☐ Other: _____

Claim Rejections - 35 USC § 112

1. Claims 23-66 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention:

a) Claims 23, 40, and 50: is any of the titration acid actually in the buffer or is the titration acid a reagent that is consumed and is not in the final product (product-by-process)?

2. Note that dependent claims will have the deficiencies of base and intervening claims.

Double Patenting

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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Double Patenting Rejections Based on U.S. Patent No. 5,922,185

4. Claims 23-28 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claim 12 of U.S. Patent No. 5,922,185.

Addressing Claim 23, although the conflicting claims are not identical, they are not patentably distinct from each other because the scope of Claim 23 essentially encompasses the scope of Claim 12. Although Claim 23 claims a gel electrophoresis system and Claim 12 claims an apparatus that is part of an electrophoresis system, it would have been obvious to one with ordinary skill in the art at the time the invention was made to use the apparatus of Claim 12 in an electrophoresis system because the claim itself states that this is its intended use.

Addressing Claim 24, Claim 12 of U.S. Patent No. 5,922,185 states that the buffer is continuous.

Addressing Claim 25, most, if not all, of the claimed acids are listed in Claim 12 of U.S. Patent No. 5,922,185.

Addressing Claims 26-28, all of the claimed acids are listed in Claim 12 of U.S. Patent No. 5,922,185.

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5. Claim 29 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claim 15 of U.S. Patent No. 5,922,185. Claim 24, from which Claim 29 depends, has been addressed above. The amine claimed in Claim 29 is claimed in Claim 15 of U.S. Patent No. 5,922,185.

6. Claims 30-32 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claim 16 of U.S. Patent No. 5,922,185. Claim 24, from which Claims 30-32 depend, has been addressed above. A denaturing agent, urea and formamide claimed in Claims 30-32 are claimed in Claim 16 of U.S. Patent No. 5,922,185.

7. Claim 33 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claim 16 of U.S. Patent No. 5,922,185. Claim 24, from which Claim 30 depends, has been addressed above. Although not claimed, it would have been obvious to one with ordinary skill in the art at the time the invention was made to use ethylenediamine-tetracetic acid (EDTA) because it is a well-known buffering agent that is commonly used in electrophoresis buffer systems. It is also known in the art to use EDTA with denaturant to prevent Mg^{++} from binding to nucleic acid.

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8. Claim 34 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claim 19 of U.S. Patent No. 5,922,185. Claim 24, from which Claim 34 depends, has been addressed above. An anode buffer is required in Claim 19 of U.S. Patent No. 5,922,185.

9. Claim 35 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claim 20 of U.S. Patent No. 5,922,185. Claim 34, from which Claim 35 depends, has been addressed above. Tris is required in Claim 20 of U.S. Patent No. 5,922,185.

10. Claim 36 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claim 19 of U.S. Patent No. 5,922,185. Claim 34, from which Claim 36 depends, has been addressed above. HCl is a well-known acid that is commonly used in electrophoresis. Barring evidence to the contrary, such as unexpected results, one with ordinary skill in the art at the time of the invention would use an acid that will not adversely affect the separation and that will provide the desired pH.

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11. Claim 37 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claim 17 of U.S. Patent No. 5,922,185. Claim 24, from which Claim 37 depends, has been addressed above. A cathode buffer is required in Claim 17 of U.S. Patent No. 5,922,185.

12. Claim 38 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claim 18 of U.S. Patent No. 5,922,185. Claim 37, from which Claim 38 depends, has been addressed above. Tris is required in Claim 18 of U.S. Patent No. 5,922,185.

13. Claims 40-44 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claim 12 of U.S. Patent No. 5,922,185.

Addressing Claim 40, although the conflicting claims are not identical, they are not patentably distinct from each other because the scope of Claim 40 essentially encompasses the scope of Claim 12. Although Claim 40 claims only a gel comprising a gel buffer and Claim 12 claims an electrophoresis apparatus comprising a gel and gel buffer, it would have been obvious to one with ordinary skill in the art at the time the invention was made to use the apparatus of Claim 40 in an electrophoresis system because the claim itself states that it is intended for the gel to be used for electrophoresis separations.

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Addressing Claim 41, most, if not all, of the claimed acids are listed in Claim 12 of U.S. Patent No. 5,922,185.

Addressing Claims 42-44, all of the claimed acids are listed in Claim 12 of U.S. Patent No. 5,922,185.

14. Claim 45 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claim 15 of U.S. Patent No. 5,922,185. Claim 40, from which Claim 45 depends, has been addressed above. The amine claimed in Claim 45 is claimed in Claim 15 of U.S. Patent No. 5,922,185.

15. Claims 46-48 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claim 16 of U.S. Patent No. 5,922,185. Claim 40, from which Claims 46-48 depend, has been addressed above. A denaturing agent, urea and formamide claimed in Claims 46-48 are claimed in Claim 16 of U.S. Patent No. 5,922,185.

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16. Claim 49 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claim 16 of U.S. Patent No. 5,922,185. Claim 40, from which Claim 49 depends, has been addressed above. Although not claimed, it would have been obvious to one with ordinary skill in the art at the time the invention was made to use ethylenediamine-tetracetic acid (EDTA) because it is a well-known buffering agent that is commonly used in electrophoresis buffer systems. It is also known in the art to use EDTA with denaturant to prevent Mg^{++} from binding to nucleic acid.

17. Claims 50 and 52-55 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claim 12 of U.S. Patent No. 5,922,185.

Addressing Claim 50, although the conflicting claims are not identical, they are not patentably distinct from each other because the scope of Claim 50 essentially encompasses the scope of Claim 12. Anyone who uses the electrophoresis apparatus of Claim 12 for performing electrophoresis is practicing the method of Claim 50.

Addressing Claim 52, most, if not all, of the claimed acids are listed in Claim 12 of U.S. Patent No. 5,922,185.

Addressing Claims 53-55, all of the claimed acids are listed in Claim 12 of U.S. Patent No. 5,922,185.

18. Claim 51 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claim 17 of U.S. Patent No. 5,922,185. Claim 50, from which Claim 51 depends, has been addressed above. A cathode buffer is claimed in Claim 17 of U.S. Patent No. 5,922,185. Since Claim 12 requires that the buffer be continuous the gel and cathode buffer will be the same.
19. Claim 56 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claim 15 of U.S. Patent No. 5,922,185. Claim 51, from which Claim 56 depends, has been addressed above. The amine claimed in Claim 56 is claimed in Claim 15 of U.S. Patent No. 5,922,185.
20. Claims 57-59 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claim 16 of U.S. Patent No. 5,922,185. Claim 51, from which Claims 57-59 depend, has been addressed above. A denaturing agent, urea and formamide claimed in Claims 57-59 are claimed in Claim 16 of U.S. Patent No. 5,922,185.
21. Claim 60 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claim 16 of U.S. Patent No. 5,922,185. Claim 51, from which Claim 60 depends, has been addressed above. Although not claimed in Claim 16 of U.S. Patent No. 5,922,185, it is obvious to one with ordinary skill in the art at the time the invention was made to use ethylenediamine-tetracetic acid (EDTA) because it is a denaturing agent that is

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commonly used in electrophoresis buffer systems. It is also known in the art to use EDTA with denaturant to prevent Mg^{++} from binding to nucleic acid.

22. Claim 61 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claim 19 of U.S. Patent No. 5,922,185. Claim 51, from which Claim 61 depends, has been addressed above. An anode buffer is required in Claim 19 of U.S. Patent No. 5,922,185.

23. Claim 62 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claim 20 of U.S. Patent No. 5,922,185. Claim 61, from which Claim 62 depends, has been addressed above. Tris is required in Claim 20 of U.S. Patent No. 5,922,185.

24. Claim 63 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claim 19 of U.S. Patent No. 5,922,185. Claim 61, from which Claim 63 depends, has been addressed above. HCl is a well-known acid that is commonly used in electrophoresis. Barring evidence to the contrary, such as unexpected results, one with ordinary skill in the art at the time of the invention would use an acid that will not adversely affect the separation and that will provide the desired pH.

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25. Claim 64 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claim 17 of U.S. Patent No. 5,922,185. Claim 61, from which Claim 64 depends, has been addressed above. A cathode buffer is required in Claim 17 of U.S. Patent No. 5,922,185.

26. Claim 65 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claim 18 of U.S. Patent No. 5,922,185. Claim 64, from which Claim 65 depends, has been addressed above. This is required in Claim 18 of U.S. Patent No. 5,922,185.

Double Patenting Rejections Based on U.S. Patent No. 6,162,338

27. Claim 23 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claim 1 of U.S. Patent No. 6,162,338.

Addressing Claim 23, although the conflicting claims are not identical, they are not patentably distinct from each other because the scope of Claim 23 encompasses the scope of Claim 1 of U.S. Patent No. 6,162,338.

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28. Claim 40 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claim 1 of U.S. Patent No. 6,162,338.

Addressing Claim 40, although the conflicting claims are not identical, they are not patentably distinct from each other because the gel of Claim 1 of U.S. Patent No. 6,162,338 is within the scope of Claim 40.

29. Claim 41 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claim 4 of U.S. Patent No. 6,162,338. Claim 40, from which Claim 41 depends, has been addressed above. Hydrochloric acid and acetic acid are claimed in Claim 4.

30. Claim 45 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claim 2 of U.S. Patent No. 5,922,185. Claim 40, from which Claim 45 depends, has been addressed above. The amine claimed in Claim 45 is claimed in Claim 2 of U.S. Patent No. 6,162,338.

31. Claim 50 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claim 16 of U.S. Patent No. 6,162,338.

Addressing Claim 50, although the conflicting claims are not identical, they are not patentably distinct from each other because the scope of Claim 50 encompasses the scope of Claim 16 of U.S. Patent No. 6,162,338.

Claim Rejections - 35 USC § 102

32. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

33. Claim 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Stanescu et al. ("Proteoglycan Electrophoresis on Horizontal Submerged Polyacrylamide-agarose Gels," *Connective Tissue Research*, 1987, vol. 16, pp. 71-77).

Addressing Claims 23, for the claimed limitations see the entire section entitled *Electrophoresis on horizontal submerged polyacrylamide-agarose gels* from page 73 to page 74. Note that Tris has a pK_a of 8.1 (page 1111 of 1992May1993 ICN catalog), which is near neutrality.

34. Claim 23 is rejected under 35 U.S.C. 102(b) as being anticipated by Sehajpal et al. ("Detection of GLO-I Isozymes in Human Blood by a Rapid Method," *Annals of Biology*, vol. 2, no. 1, pp. 90-92, 1986).

Addressing Claim 23, for the claimed limitations see the second paragraph on page 90. Note that Tris has a pK_a of 8.1 (page 1111 of 1992May1993 ICN catalog), which is near neutrality. Also, for Claim 40, one with ordinary skill in the art at the time of the invention

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would assume that the gel is uniformly saturated with buffer, that is, not a buffer gradient gel, unless so stated.

35. Claims 23 and 40 are rejected under 35 U.S.C. 102(b) as being anticipated by Salvatore et al. ("Agarose Gel Electrophoresis System for the Separation of Antibiotics used in Animal Agriculture," *Analyst*, March 1993, vol. 18, pp. 281-287).

Addressing Claims 23 and 40, for the claimed limitations see the abstract and the *Reagents* subsection of the *Experimental* section on page 118. Also, for Claim 40, one with ordinary skill in the art at the time of the invention would assume that the gel is uniformly saturated with buffer, that is, not a buffer gradient gel, unless so stated.

36. Claims 23 and 40 are rejected under 35 U.S.C. 102(b) as being anticipated by Chevigné et al. (US 5,246,558).

Addressing Claims 23 and 40, for the claimed limitations see Claims 8-11 together. Also, for Claim 40, one with ordinary skill in the art at the time of the invention would assume that the gel is uniformly saturated with buffer, that is, not a buffer gradient gel, unless so stated.

Claim Rejections - 35 USC § 103

37. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

38. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

39. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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40. Claims 24, 25, 30, 32, 34, 35, 37, 38, 40, 41, 46, 50-52, 57, 59, 61, 62, 64, and 65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stanescu et al. ("Proteoglycan Electrophoresis on Horizontal Submerged Polyacrylamide-agarose Gels," *Connective Tissue Research*, 1987, vol. 16, pp. 71-77).

Addressing Claim 24, Stanescu et al. teach a gel electrophoresis system comprising a separating electrophoresis gel comprising agarose; and a gel buffer comprising an organic amine with pK_a near neutrality and titrated with an acid, the gel buffer having a pH between pH 5.5 and pH 7.5. These limitations are taught in the section entitled *Electrophoresis on horizontal submerged polyacrylamide-agarose gels* from page 73 to page 74. Note that Tris has a pK_a of 8.1 (page 1111 of 1992May1993 ICN catalog), which is near neutrality.

Although Stanescu et al. do not specifically state that the system is a continuous buffer system, it would have been obvious to one with ordinary skill in the art that this is so because nowhere in the disclosure is a discontinuous system suggested or implied; only one buffer is disclosed as being used in the electrophoresis system.

Addressing Claims 25, 41, and 52, the titrating acid is acetic acid (top line of page 74).

Addressing Claims 30, 32, 46, 48, 57, and 59 urea is taught in the second full paragraph on page 74.

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Addressing Claims 34, 35, 61, and 62 since only one buffer is disclosed, one with ordinary skill in the art would understand that Stanescu et al. uses an anode buffer that is the same as the gel buffer, which is Tris.

Addressing Claims 37, 38, 51, 64, and 65 since only one buffer is disclosed, one with ordinary skill in the art would understand that Stanescu et al. use a cathode buffer that is the same as the gel buffer, which is Tris.

Addressing Claim 40, Stanescu et al. teach a separating electrophoresis gel comprising agarose in contact with a gel buffer comprising an organic amine with pK_a near neutrality and titrated with an acid, the gel buffer having a pH between pH 5.5 and pH 7.5. These limitations are taught in the section entitled *Electrophoresis on horizontal submerged polyacrylamide-agarose gels* from page 73 to page 74. Note that Tris has a pK_a of 8.1 (page 1111 of 1992May1993 ICN catalog), which is near neutrality.

Also, although not stated, one with ordinary skill in the art at the time of the invention would assume that the gel is uniformly saturated with buffer, that is, the gel is not a buffer gradient gel, unless so stated.

Addressing Claim 50, Stanescu et al. teach a method for performing electrophoresis comprising

applying a potential difference across a separating electrophoresis gel comprising agarose and a gel buffer comprising an organic amine with pK_a near neutrality and titrated with an acid,

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the gel buffer having a pH between pH 5.5 and pH 7.5. These limitations are taught in the section entitled *Electrophoresis on horizontal submerged polyacrylamide-agarose gels* from page 73 to page 74. Note that Tris has a pK_a of 8.1 (page 1111 of 1992May1993 ICN catalog), which is near neutrality.

41. Claims 24, 30, 34, 35, 37-40, 46, 50, 51, 57, 61, 62, and 64-66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sehajpal et al. (Detection of GLO-I Isozymes in Human Blood by a Rapid Method," *Annals of Biology*, vol. 2, no. 1, pp. 90-92, 1986).

Addressing Claim 24, Sehajpal et al. teach a gel electrophoresis system comprising a separating electrophoresis gel comprising agarose; and

a gel buffer comprising an organic amine with pK_a near neutrality and titrated with an acid, the gel buffer having a pH between pH 5.5 and pH 7.5. These limitations are taught in the second paragraph on page 90. Note that Tris has a pK_a of 8.1 (page 1111 of 1992May1993 ICN catalog), which is near neutrality.

Although Sehajpal et al. do not specifically state that the system is a continuous buffer system, it would have been obvious to one with ordinary skill in the art that this is so because nowhere in the disclosure is a discontinuous system suggested or implied; only one buffer is disclosed as being used in the electrophoresis system.

Addressing Claims 30 and 46, β -mercaptoethanol, a protein denaturant, is taught in the second paragraph on page 90.

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Addressing Claims 34, 35, 61, and 62 since only one buffer is disclosed, one with ordinary skill in the art would understand that Sehajpal et al. uses an anode buffer that is the same as the gel buffer, which is Tris.

Addressing Claims 37, 38, 51, 64, and 65 since only one buffer is disclosed, one with ordinary skill in the art would understand that Sehajpal et al. use a cathode buffer that is the same as the gel buffer, which is Tris.

Addressing Claims 39 and 66, Sehajpal et al. use lithium hydroxide; however, barring evidence to the contrary, such as unexpected results, lithium hydroxide and sodium hydroxide will be considered equivalent since they are similar strong bases and lithium and sodium are both alkali metals.

Addressing Claim 40, Sehajpal et al. teach a separating electrophoresis gel comprising agarose in contact with

a gel buffer comprising an organic amine with pK_a near neutrality and titrated with an acid, the gel buffer having a pH between pH 5.5 and pH 7.5. These limitations are taught in the second paragraph on page 90. Note that Tris has a pK_a of 8.1 (page 1111 of 1992May1993 ICN catalog), which is near neutrality.

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Also, although not stated, one with ordinary skill in the art at the time of the invention would assume that the gel is uniformly saturated with buffer, that is, not a buffer gradient gel, unless so stated.

Addressing Claim 50, Sehajpal et al. teach a method for performing electrophoresis comprising

applying a potential difference across a separating electrophoresis gel comprising agarose and a gel buffer comprising an organic amine with pK_a near neutrality and titrated with an acid, the gel buffer having a pH between pH 5.5 and pH 7.5. These limitations are taught in the second paragraph on page 90. Note that Tris has a pK_a of 8.1 (page 1111 of 1992May1993 ICN catalog), which is near neutrality.

42. Claims 24, 34, 35, 37, 38, 40, 50, 51, 61, 62, 64, and 65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Salvatore et al. ("Agarose Gel Electrophoresis System for the Separation of Antibiotics used in Animal Agriculture," *Analyst*, March 1993, vol. 18, pp. 281-287).

Addressing Claim 24, Salvatore et al. teach a gel electrophoresis system comprising a separating electrophoresis gel comprising agarose; and a gel buffer comprising an organic amine with pK_a near neutrality and titrated with an acid, the gel buffer having a pH between pH 5.5 and pH 7.5. These limitations are taught in the abstract and the *Reagents* subsection of the *Experimental* section on page 118.

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Although Salvatore et al. do not specifically state that the system is a continuous buffer system, it would have been obvious to one with ordinary skill in the art that this is so because nowhere in the disclosure is a discontinuous system suggested or implied; only one buffer is disclosed as being used in the electrophoresis system.

Addressing Claims 34, 35, 61, and 62 since only one buffer is disclosed, one with ordinary skill in the art would understand that Salvatore et al. uses an anode buffer that is the same as the gel buffer, which is Tris.

Addressing Claims 37, 38, 51, 64, and 65 since only one buffer is disclosed, one with ordinary skill in the art would understand that Salvatore et al. uses a cathode buffer that is the same as the gel buffer, which is Tris.

Addressing Claim 40, Salvatore et al. teach a separating electrophoresis gel comprising agarose in contact with

a gel buffer comprising an organic amine with pK_a near neutrality and titrated with an acid, the gel buffer having a pH between pH 5.5 and pH 7.5. These limitations are taught in the abstract and the *Reagents* subsection of the *Experimental* section on page 118.

Also, although not stated, one with ordinary skill in the art at the time of the invention would assume that the gel is uniformly saturated with buffer, that is, the gel is not a buffer gradient gel, unless so stated.

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Addressing Claim 50, Salvatore et al. teach a method for performing electrophoresis comprising

applying a potential difference across a separating electrophoresis gel comprising agarose and a gel buffer comprising an organic amine with pK_a near neutrality and titrated with an acid, the gel buffer having a pH between pH 5.5 and pH 7.5. These limitations are taught in the abstract and the *Reagents* subsection of the *Experimental* section on page 118.

Note that Tris has a pK_a of 8.1 (page 1111 of 1992May1993 ICN catalog), which is near neutrality.

43. Claims 24, 34, 35, 37-40, 50, 51, 61, 62, and 64-66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chevigné et al. (US 5,246,558).

Addressing Claim 24, Chevigné et al. teach a gel electrophoresis system comprising a separating electrophoresis gel comprising agarose; and a gel buffer comprising an organic amine with pK_a near neutrality and titrated with an acid, the gel buffer having a pH between pH 5.5 and pH 7.5. These limitations are implied by Claims 8-11 of Chevigné et al. taken together.

Although Chevigné et al. do not specifically state that the system is a continuous buffer system, it would have been obvious to one with ordinary skill in the art that this is so because nowhere in the disclosure is a discontinuous system suggested or implied; only one buffer is disclosed as being used in the electrophoresis system..

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Addressing Claims 34, 35, 61, and 62 since only one buffer is disclosed, one with ordinary skill in the art would understand that Chevigné et al. uses an anode buffer that is the same as the gel buffer, which is Tris.

Addressing Claims 37, 38, 51, 64, and 65 since only one buffer is disclosed, one with ordinary skill in the art would understand that Chevigné et al. uses a cathode buffer that is the same as the gel buffer, which is Tris.

Addressing Claims 39 and 66, sodium hydroxide is disclosed in Claim 11.

Addressing Claim 40, Chevigné et al. teach a separating electrophoresis gel comprising agarose in contact with

a gel buffer comprising an organic amine with pK_a near neutrality and titrated with an acid, the gel buffer having a pH between pH 5.5 and pH 7.5. These limitations are implied by Claims 8-11 of Chevigné et al. taken together.

Also, although not stated, one with ordinary skill in the art at the time of the invention would assume that the gel is uniformly saturated with buffer, that is, the gel is not a buffer gradient gel, unless so stated.

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Addressing Claim 50, Chevigné et al. teach a method for performing electrophoresis comprising


applying a potential difference across a separating electrophoresis gel comprising agarose and a gel buffer comprising an organic amine with pK_a near neutrality and titrated with an acid, the gel buffer having a pH between pH 5.5 and pH 7.5. These limitations are implied by Claims 8-11 of Chevigné et al. taken together.

Note that Tris has a pK_a of 8.1 (page 1111 of 1992May1993 ICN catalog), which is near neutrality.

44. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALEX NOGUEROLA whose telephone number is (703) 305-5686. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, JILL WARDEN can be reached on (703) 308-4037. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9310 for regular communications and (703) 872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.


Alex Noguefola
September 28, 2002